## S. 2029

To amend title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.

## IN THE SENATE OF THE UNITED STATES

**SEPTEMBER 6, 2007** 

Mr. Grassley (for himself, Mr. Kohl, Mr. Kennedy, Mrs. McCaskill, Mr. Schumer, and Ms. Klobuchar) introduced the following bill; which was read twice and referred to the Committee on Finance

## A BILL

To amend title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Physician Payments
- 5 Sunshine Act of 2007".

1	SEC. 2. QUARTERLY TRANSPARENCY REPORTS FROM MAN-
2	UFACTURERS OF COVERED DRUGS, DEVICES,
3	OR MEDICAL SUPPLIES UNDER MEDICARE,
4	MEDICAID, OR SCHIP.
5	Part A of title XI of the Social Security Act (42
6	U.S.C. 1301 et seq.) is amended by inserting after section
7	1128F the following new section:
8	"SEC. 1128G. QUARTERLY TRANSPARENCY REPORTS FROM
9	MANUFACTURERS OF COVERED DRUGS, DE-
0	VICES, OR MEDICAL SUPPLIES UNDER MEDI-
1	CARE, MEDICAID, OR SCHIP.
2	"(a) Reporting of Payments or Other Trans-
3	FER OF VALUE.—On January 1, 2008, and the first day
4	of each fiscal year quarter beginning thereafter, each man-
5	ufacturer of a covered drug, device, or medical supply who
6	provides a payment or other transfer of value, directly,
7	indirectly, or through an agent, subsidiary, or other third
8	party, to a physician, or to an entity that a physician is
9	employed by, has tenure with, or has an ownership interest
20	in, shall submit to the Secretary, in such electronic form
21	as the Secretary shall require, the following:
22	"(1) The name of the physician, and if a pay-
23	ment or other transfer of value was provided to an
24	entity that the physician is employed by, has tenure
25	with, or has an ownership interest in, the entity.
26	"(2) The address of—

1	"(A) the physician's office; and
2	"(B) in the case of an entity required to
3	be named under paragraph (1), the primary
4	place of business or headquarters for the entity.
5	"(3) The facility with which the physician is af-
6	filiated, if any.
7	"(4) The value of the payment or other transfer
8	of value.
9	"(5) The date on which the payment or other
10	transfer of value was provided.
11	"(6) A description of the nature of the payment
12	or other transfer of value, indicated (as appropriate
13	for all that apply) as—
14	"(A) compensation;
15	"(B) food, entertainment, or gifts;
16	"(C) trips or travel;
17	"(D) a product or other item provided for
18	less than market value;
19	"(E) participation in a medical conference,
20	continuing medical education, or other edu-
21	cational or informational program or seminar,
22	provision of materials related to such a con-
23	ference or educational or informational program
24	or seminar, or remuneration for promoting or

participating in such a conference or edu-1 2 cational or informational program or seminar; "(F) product rebates or discounts; 3 "(G) consulting fees or honoraria; or 4 "(H) any other economic benefit, as de-6 fined by the Secretary. 7 "(7) The medical issue or condition addressed, 8 if any, that was the basis for the payment or trans-9 fer. 10 "(b) Annual Summary Report.—Each manufacturer of a covered drug, device, or medical supply that is 12 required to submit information under subsection (a) during a year shall submit a report to the Secretary not later than December 31 of the year that summarizes, in such 14 15 electronic form as the Secretary shall specify, each submission of information under subsection (a) made by the man-16 17 ufacturer during the year. 18 "(c) Penalty for Noncompliance.—Any manufacturer of a covered drug, device, or medical supply that 19 20 fails to submit information required under subsection (a) 21 or (b) in accordance with regulations promulgated to carry out such subsection, shall be subject to a civil money pen-23 alty of not less than \$10,000, but not more than \$100,000, for each such failure. Such penalty shall be im-

posed and collected in the same manner as civil money

- 1 penalties under subsection (a) of section 1128A are im-
- 2 posed and collected under that section.
- 3 "(d) Public Availability.—Not later than June 1,
- 4 2008, the Secretary shall establish procedures to ensure
- 5 that the information reported under subsection (a) and the
- 6 summary reports submitted under subsection (b) are read-
- 7 ily accessible to the public through an Internet website
- 8 that is easily searchable, downloadable, and understand-
- 9 able.
- 10 "(e) Report to Congress.—Not later than April
- 11 1 of each year beginning with 2009, the Secretary shall
- 12 submit to Congress a report that includes the following:
- 13 "(1) The information submitted under sub-
- sections (a) and (b) during the preceding year, ag-
- 15 gregated for each manufacturer of a covered drug,
- device, or medical supply that submitted such infor-
- 17 mation during such year.
- 18 "(2) A description of any enforcement actions
- taken to carry out this section, including any pen-
- alties imposed under subsection (c), during the pre-
- ceding year.
- 22 "(f) Definitions.—In this section:
- 23 "(1) COVERED DRUG, DEVICE, OR MEDICAL
- 24 SUPPLY.—The term 'covered drug, device, or med-
- 25 ical supply' means any drug, biological product, de-

1	vice, or medical supply for which payment is avail-
2	able under title XVIII or a State plan under title
3	XIX or XXI (or a waiver of such a plan).
4	"(2) Manufacturer of a covered drug,
5	DEVICE, OR MEDICAL SUPPLY.—The term 'manufac-
6	turer of a covered drug, device, or medical supply'
7	means any entity with annual gross revenues that
8	exceed \$100,000,000, which is engaged in—
9	"(A) the production, preparation, propaga-
10	tion, compounding, conversion, or processing of
11	a covered drug, device, or medical supply; or
12	"(B) the packaging, repackaging, labeling,
13	relabeling, or distribution of a covered drug, de-
14	vice, or medical supply.
15	"(3) Payment or other transfer of
16	VALUE.—
17	"(A) In general.—The term 'payment or
18	other transfer of value' means a transfer of
19	anything of value that exceeds \$25, and in-
20	cludes any compensation, gift, honorarium,
21	speaking fee, consulting fee, travel, discount,
22	cash rebate, or services.
23	"(B) Exclusions.—Such term does not
24	include the following:

1	"(i) Product samples that are in-
2	tended for patients.
3	"(ii) A payment or other transfer of
4	value made for the general funding of a
5	clinical trial.
6	"(iii) A transfer of anything of value
7	to a physician when the physician is a pa-
8	tient and not acting in his or her profes-
9	sional capacity.
10	"(4) Physician.—The term 'physician' has the
11	meaning given that term in section 1861(r).".

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